Remarks

Claims 1 and 11 have been amended to specify that the claimed polymer is a poly(ester-anhydride) comprises random ester or amide bonds along the polymer chain. Support for these amendments can be at least be found at page 8, lines 26-27, page 13 lines 1-19, and page 15, lines 11-13, of the specification, as well as Figure 1.

Rejection Under 35 U.S.C. § 112, first paragraph

Claims 1-9 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled for biologically active or small drug molecules. Claims 1-3 and 7-10 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled for all fatty acids and all dicarboxylic acids. Applicants respectfully traverse these rejections to the extent that they are applied to the claims as amended.

Legal Standard

The Court of Appeals for the Federal Circuit (CAFC) has described the legal standard for enablement under § 112, first paragraph, as whether one skilled in the art could make and use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *See, e.g., Amgen v. Hoechst Marion Roussell* 314 F.3d 1313 (Fed. Cir. 2003) and *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 42 USPQ2D 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). *See also In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970); *United States v. Telectronics, Inc.*, 857 F.2d 778 (Fed. Cir. 1988); and *In re Stephens*, 529 F.2d 1343, 188 USPQ 659 (CCPA 1976). The fact that experimentation may be complex does not

necessarily make it undue, if the art typically engages in such experimentation. *M.I.T. v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). The adequacy of a specification's description is not necessarily defeated by the need for some experimentation to determine the properties of a claimed product. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F3d 956, 965-966, 63 USPQ2d 1609, 1614 (Fed. Cir. 2002). In addition, a patent need not teach, and preferably omits, what is well known in the art. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *citing Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). Thus, information that is conventional or well-known to one of ordinary skill in the art need not be disclosed by the specification.

Whether the disclosure is enabling is a legal conclusion based upon several underlying factual inquiries. *See In re Wands*, 858 F.2d 731, 735, 736-737, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir.1988). As set forth in *Wands*, the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and the (8) breadth of the claims. In cases that involve unpredictable factors, "the scope of the enablement obviously varies inversely with the degree of unpredictability of the factors involved." *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount

of experimentation "must not be unduly extensive." *In re Atlas Powder Co., v. E.I. DuPont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir.1984). Further, patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Analysis

The examiner alleges that the specification does not provide reasonable enablement for all biologically active agents or small drug molecules. In addition the examiner alleges that the specification does not provide reasonable enablement for all fatty acids and all dicarboxylic acids. The claims as amended are directed to a drug delivery composition containing a polyanhydride having random ester or amide bonds along the backbone and a biologically active agent.

As detailed above, the test for enablement is whether one of ordinary skill in the art could make and use the claimed compositions and methods without *undue* experimentation. Whether or not experimentation is undue is a conclusion based on weighing *many* factors, not just a *single* factor, as presented by the Examiner. There is no requirement that all embodiments within a genus be enabled to meet the standard for enablement.

A proper analysis of the *Wands* factors shows that the claimed compositions and methods are enabled. As discussed in detail below, based on the amount of guidance provided in the specification, the quantity of experimentation necessary, the presence of working examples, and the breadth of the claims, one of ordinary skill in the art would be able to make and use the claimed compositions without undue experimentation.

The amount of direction or guidance presented and the quantity of experimentation necessary

Patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

The Examiner alleges that the specification as filed "while being enabling for ricinoleic acid and dimer erucic acid, dimer oleic acid and non-linear fatty acid derivative of ricinoleic acid, fumarate or succinate as the dicarboxylic acids, does not provide reasonable enablement for all fatty acids and all dicarboxylic acids". The Examiner is applying the wrong legal standard. Applicants are not required to show working Examples, studies performed on other or all embodiments, or information that is well known to one skilled in the art. The standard is that one of ordinary skill in the art could practice the claimed invention without undue experimentation.

First, the synthetic step to react a fatty acid with a dicarboxylic acid is well known and characterized. One skilled in the art would have no difficulty in determining if the reaction between the two acids formed the polymer specified in claim 1. Moreover, as the examiner points out, the specification provides numerous details of how to make and use the claimed subject matter from a variety of acids such as ricinoleic acid and dimer erucic acid, dimer oleic acid and non-linear fatty acid derivative of ricinoleic acid, fumarate or succinate as the dicarboxylic acids. Thus, one of skill in the art would not engage in undue experimentation in determining if a specific fatty acid would react with a specific dicarboxylic acid to form a

polymer since, as the examiner points out, a variety of examples are presented in the specification.

The Examiner also alleges that the specification as filed "while being enabling for paclitaxel, cisplatin and/or carboplatin, does not provide reasonable enablement for biologically active agent or small drug molecules". The incorporation of an active agent into a polymer matrix is well known in the art. Again, the Examiner is applying the wrong legal standard. Applicants are not required to show working Examples, studies performed on other active agents, or information that is well known to one skilled in the art. The standard is that one of ordinary skill in the art could practice the claimed invention without undue experimentation. As the examiner notes, there are examples of the encapsulation of paclitaxel, cisplatin and carboplatin described in the specification. Also described (but not noted by the examiner) in examples 2, 11, and 13 is the encapsulation of additional small drug molecules such as methotrexate, 5-FU, aminocycline, gentamicin, amphotericin B, risporidal, tetracycline, chlorhexidin, bupivacaine and gentamicin. The examiner alleges that the "recitation of broad categories of drugs, namely, antibacterial, anti-inflammatory, anticancer, antidepressants, analgesics and local anesthetics is an invitation to experiment with all species of broad categories". The examiner has provided no technical reason why the polymer of claim 1 is unable to incorporate and deliver other classes of drugs. The fact that the three examples the examiner chose from the specification are coincidentally anticancer agents does not make other classes of drugs nonenabled. In fact, the examples have shown the use of other classes of drugs, such as antibiotics (tetracycline, gentamicin, chlorhexidin), anti-psychotics (risporidal),

antifungals (amphotericin B), and anesthetics (bupivacaine). The specification provides detailed enablement for incorporating multiple active agents into the polymer. The examiner has provided no reason why these example would not be enabling and predictive of methods for incorporation and delivery of other drugs. There is no evidence of record that one of skill in the art would have to engage in undue experimentation to incorporate another drug into the polymer, since, as the examiner points out, a variety of examples are presented in the specification.

The presence or absence of working examples

Although working examples are *not* required to establish enablement, examples 2, 3, 4, 5, 7 and 10 disclose examples of reacting fatty acids and dicarboxylic acids to form polymers. Pages 13-15 disclose several suitable fatty acids and dicarboxylic acids. Examples 2, 4, 5, 7, 8, 11, 12, and 13 disclose the incorporation of small drug molecules into a polymer matrix.

The nature of the invention

The nature of the invention is a drug delivery composition. The composition comprises a biodegradable poly(ester-anhydride) having *random ester or amide bonds* and a biologically active agent. The random ester or amide bonds modify the lattice packing of the polymer to produce superior biodegradation properties.

The state of the prior art and the predictability or lack thereof in the art

The examiner states on the bottom of page 4 that "There is no predictability that... all fatty acids and *all biologically active agents would form ester anhydride bond* with any/all dicarboxylic acids.". The examiner does not appear to understand the claims. The claims are directed to a drug delivery composition which contains a biodegradable polymer matrix non-

covalently *loaded* with an active agent (Page 8, lines 17-21). There is *no* covalent linkage between the biologically active agent and the polymeric matrix as the examiner suggests. The active agent is encapsulated (with or without a stabilizing agent) into the polymeric matrix and is released into the body by diffusion and polymer degradation. Although there is no requirement for working examples, there are several examples showing different biologically active agents incorporated into various polymers. It should be noted that the chemical structure of the biological agent is *not* altered, rather the drug is encapsulated. Encapsulation does not typically alter the chemical structure of the drug but only the way in which it is delivered. In example 9, local administration via the polymerically encapsulated agent is shown to be more effective as compared to systemic administration of the same agent. Although the examples provided target cancer, there are a variety of ailments disclosed in the specification (treated by a multitude of biologically active agents) that can benefit from the localized administration of one or more active agents.

In another section, the examiner alleges that "while chemical reactions are accompanied with a high level of predictability, that there is no full predictability that all fatty acids would react with dicarboxylic acids because of the vast array or dicarboxylic acids, known and yet to be discovered, and the same is true for fatty acids and then the encapsulability of all biologically active agents within the polymer". The examiner herself states that "chemical reactions are accompanied with a high level of predictability". As stated above, the synthetic step to react a fatty acid with a dicarboxylic acid is well known. The standard is that one of ordinary skill in the art could practice the claimed invention without undue experimentation. One skilled in the art

would have no difficulty in determining if the reaction between the two acids formed the polymer specified in claim 1 and therefore the rejection should be withdrawn.

The relative skill of those in the art

The relative skill of those in the art is high. The incorporation of a drug into a polymer matrix is well known in the art. The steps to forming polyanhydrides via condensation reactions are also well known. In addition, the distinguishing details of the synthesis of the polymers of claim 1 are disclosed in the specification. One of skill in the art would have no difficulty in making and using the polymer of claim 1.

The breadth of the claims.

Finally, the examiner alleges that "the protection sought is broader than the enabling disclosure for the biologically active agents, fatty acids and dicarboxylic acids", implying that there may be inoperable elements as the claims encompass all biologically active agents, all fatty acids and all dicarboxylic acids "some of which may not have even been discovered". While the latter may be true, it does not render the claims non-enabled. Applicants respectfully draw the Examiner's attention to MPEP § 2164.08(b) which states "[T]he presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984) (prophetic examples do not make the disclosure nonenabling). Even if the claims encompass an inoperative embodiment, which has not been

established, one of skill in the art would not engage in undue experimentation to practice the claimed methods. Therefore, the rejection should be withdrawn.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 2 and 6 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

The examiner alleges that the boundaries of "ester derivative of ricinoleic acid" and "small drug molecules" are not defined.

Legal Standard

"[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, *>415 F.3d 1303, 1313<, 75 USPQ2d 1321>, 1326< (Fed. Cir. 2005) (*en banc*). *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003) ("In the absence of an express intent to impart a novel meaning to the claim terms, the words are presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art."). It is the use of the words in the context of the written description and customarily by those skilled in the relevant art that accurately reflects both the "ordinary" and the "customary" meaning of the terms in the claims.

Analysis

The examiner alleges that the boundaries of "ester derivative of ricinoleic acid" and "small drug molecules" are not defined. These terms are common to one of ordinary skill in the art.

"Small drug molecules" are widely used to describe any active agent compound that is not a macromolecule typically having a molecular weight less than around 1000 Daltons (see the definition of small molecule drug from www.wiktionary.org a copy of which is enclosed). One of ordinary skill in the art would clearly understand the meaning of "small drug molecule" because this is a term of the art that has been in use in the industry for decades. Accordingly, claims 2 and 6 are definite.

An "ester derivative" is clear to one of ordinary skill in the art. When a synthetic chemist esterifies a molecule, the product is an "ester derivative" of the functionalized moiety. Ricinoleic acid has two functionalities that can be esterified: a hydroxyl group and an acid group. An "ester derivative of ricinoleic acid" would be when an ester is formed from either of these two moieties. One of ordinary skill in the art would clearly understand the meaning of "ester derivative of ricinoleic acid" because this is a term of the art that has been in use in the industry for decades. Accordingly, claims 2 and 6 are definite.

Rejection Under 35 U.S.C. § 102

Claims 1, 2-7 and 10 were rejected under 35 U.S.C. § 102(b) as being anticipated by Teomim et al., "Ricinoleic acid-based biopolymers" J. Biomed. Mat. Res. 45(3): 258-267 (Teomim); Domb et al., "Biopolymers as drug carriers and bioactive molecules" Acta

Polymerica 49(10-11): 526-533 (Domb 1); and U.S. Patent No. 5,171,812 to Domb et al. (Domb 2). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

The Legal Standard

For a rejection of claims to be properly founded under 35 U.S.C. § 102, it must be established that a prior art reference discloses each and every element of the claims. *Hybritech Inc. v Monoclonal Antibodies Inc.*, 231 USPQ 81 (Fed. Cir. 1986), cert. denied, 480 US 947 (1987); *Scripps Clinic & Research Found v. Genentech Inc.*, 18 USPQ2d 1001 (Fed. Cir. 1991). The Federal Circuit held in Scripps, 18 USPQ2d at 1010:

> Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . *There must be no difference* between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. (Emphasis added)

A reference that fails to disclose even one limitation will not be found to anticipate, even if the missing limitation could be discoverable through further experimentation. As the Federal Circuit held in Scripps, Id.:

> [A] finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations. The role of extrinsic evidence is to educate the decision-maker to what the reference meant to

persons of ordinary skill in the field of the invention, not to fill in the gaps in the reference.

For a prior art reference to anticipate a claim, it must enable a person skilled in the art to practice the invention. The Federal Circuit held that "a §102(b) reference must sufficiently describe the claimed invention to have placed the public in possession of it. . . [E]ven if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling." Paperless Accounting Inc v Bay Area Rapid Transit Sys., 231 USPQ 649, 653 (Fed. Cir. 1986).

Analysis

Claims 1 and 11 have been amended to specify that the claimed polymer is a poly(ester-anhydride) copolymer comprising random ester or amide bonds along the polymer chain. The random ester or amide bonds are inherent to the method by which it is synthesized (support can be at least be found at page 13 lines 1-19, page 15, lines 11-13, of the specification, as well as Figure 1).

a. Teomim

Claims 1, 2-7 and 10 were rejected under 35 U.S.C. § 102(b) as being anticipated by Teomim. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Teomim describes *polyanhydrides* that are synthesized from the homopolymerization of ricinoleic acid derivatives (functionalized with maleic and succinic anhydrides to form diacids) or the copolymerization of the ricinoleic based diacid with sebacic acid. The polymers described

in Teomim are polyanhydride copolymers that are formed from the melt condensation of diacids and contain only anhydride bonds. Any esters present (which are possible with the anhydride derivatized embodiments) are functionalities of the *monomer* and are not randomly placed in the backbone. In contrast, the claimed compositions are poly (ester or amide-anhydrides). The claimed compositions are prepared by reacting a polyanhydride with a polyfunctional organic molecule that contains at least two functional groups selected from the group consisting of hydroxyl, amine, carboxylic acid, and combinations thereof to form polyanhydrides with ester and/or amide bonds in the polymer chain (Figure 1 of the specification). These polymers are further polymerized to form higher molecular weight polymers. This creates a substantially different polymer, one *with random ester bonds* along the backbone. Teomim does not disclose poly(ester-anhydrides) with ester and/or amide bonds in the polymer chain which are terminated with aliphatic hydrocarbons. Therefore, claims 1, 2-7 and 10, as amended, are novel over Teomim.

b. Domb 1

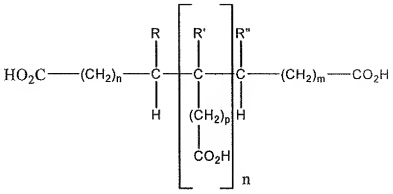
Claims 1, 2-7 and 10 were rejected under under 35 U.S.C. § 102(b) as being anticipated by Domb 1. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Domb 1 is a review article of biopolymers as drug carriers. The examiner alleges that pages 526-533 describe polyanhydrides that were derived from ricinoleic acid and sebacic acid as drug carriers with nystatin and amphotericin B. The examiner has mischaracterized the reference. There is a section where the synthesis of polyanhydrides that were derived from

ricinoleic acid and sebacic acid is disclosed. There is another section where small drug molecule conjugates (nystatin and amphotericin B) are investigated. These are two completely *different* systems described in a review article. In the section where the small drugs are investigated, the small drugs here are modified and *conjugated* to dextran (a polysaccharide). In contrast, the claimsdefine a small molecule drug encapsulated into a poly(ester-anhydride) matrix and not modified *or* conjugated. The examiner also alleges that the composition of Domb 1 "is the same composition as the composition in claim 1". This is not correct. The article only states that "polyanhydrides synthesized from non-linear hydrophobic fatty acid esters, based on ricinoleic acid, maleic acid, and sebacic acid possessed desired physicochemical properties". It is the examiner's burden to point out how "this is the same as the claimed composition" as he suggests. Domb 1 does not describe how the polymers are made. Domb 1 does not disclose poly(ester-anhydrides) with random ester and/or amide bonds in the polymer chain encasing a bioactive agent. Therefore, claims 1, 2-7 and 10, as amended, are novel over Domb 1.

*c. **Domb 2***

Domb 2 describes a polyanhydride suitable for use as a matrix material polymerized from monomers having the formula shown below:



Domb 2 does not disclose polyanhydrides containing amide or ester bonds, let alone random ester or amide bonds as required by the claims. The polymers described in Domb 2 are polyanhydrides containing anhydride bonds only. Accordingly, claim1, 2-7 and 10 are novel over Domb 2.

Rejection Under 35 U.S.C. § 103

Claims 1 and 8 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Teomim or Domb 1. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Legal Standard

Obviousness is a legal conclusion based on underlying facts of four general types, all of which must be considered by the examiner: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any objective indicia of nonobviousness. *See Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459 (1966). This standard was recently affirmed by the Supreme Court in *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007). The Court did not

totally reject the use of "teaching, suggestion, or motivation" as a factor in the obviousness analysis. Rather, the Court recognized that a showing of "teaching, suggestion, or motivation" to combine the prior art to meet the claimed subject matter could provide a helpful insight in determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a). The Supreme Court did not obviate the requirement for the references to provide some motivation to combine as applicants have done, with a reasonable expectation of success.

"Focusing on the obviousness of substitutions and differences, instead of on the invention as a whole, is a legally improper way to simplify the often difficult determination of obviousness." *Gillette Co. v. S.C. Johnson & Sons, Inc.*, 919 F.2d 720, 724, 16 U.S.P.Q.2d 1923 (Fed. Cir. 1990); *see Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1383, 231 U.S.P.Q. 81, 93 (Fed. Cir. 1986). "One cannot use hindsight reconstruction to pick and choose among isolated disclosures on the prior art to deprecate the claimed invention." *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988).

Analysis

Claims 1 and 11 were amended to clarify that the polymers have random ester or amide bonds along the polymer chain.

(a) Determining the scope and contents of the prior art

Domb 1 and Teomim are discussed above.

The examiner alleges that it would be obvious to vary the amount of ricinoleic acid to produce the desired polymer. The distinctive characteristics of the claimed compositions have been discussed above. The examiner also alleges that it would be obvious to prepare the

composition of Domb or Teomim in particulate form with the expectation of deriving the advantages of the use of particles in drug delivery. No support for these allegations has been provided. However, even if there were support, there is no teaching or enablement in any of the cited art to produce a polymer as claimed having random placement of the ester bonds along the backbone.

(b) Ascertaining the differences between the prior art and the claims

In determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 U.S.P.Q. 698 (Fed. Cir. 1983).

Teomim does not disclose or suggest each and every element of the claims.

Teomim describes *polyanhydrides* that are synthesized from the homopolymerization of ricinoleic acid derivatives (functionalized with maleic and succinic anhydrides to form diacids) or the copolymerization of such with sebacic acid. The polymers described in Teomim are polyanhydride copolymers that are formed from the melt condensation of diacids only.

In contrast, the claims compositions are poly(ester or amide-anhydrides). The claimed compositions are prepared by reacting a polyanhydride with a polyfunctional organic molecule that contains at least two functional groups selected from the group consisting of hydroxyl, amine, carboxylic acid, and combinations thereof to form polyanhydrides with ester and/or amide bonds in the polymer chain (Figure 1 of the specification). In order to establish a *prima*

facie case of obviousness, the reference must disclose each and every element of the claims. As noted above, Teomim does not disclose poly(anhydrides) with random ester or amide bonds in the polymer chain. Further, it would not have been obvious to alter the structure of the poly(anhydrides) of Teomim to place random ester and amide bonds in the backbone to achieve the different structural and physical characteristics associated with the claimed polymer. Therefore, Teomim does not disclose every element of the claims. Therefore, claims 1 and 8, as amended, are not obvious over Teomim.

Domb 1 does not disclose or suggest each and every element of the claims.

Domb 1 states that "polyanhydrides synthesized from non-linear hydrophobic fatty acid esters, based on ricinoleic acid, maleic acid, and sebacic acid possessed desired physicochemical properties". In contrast, the claimed compositions are poly(ester-anhydrides). The claimed compositions are prepared by reacting a polyanhydride with a polyfunctional organic molecule that contains at least two functional groups selected from the group consisting of hydroxyl, amine, carboxylic acid, and combinations thereof to form polyanhydrides with ester and/or amide bonds in the polymer chain (Figure 1 of the specification). In order to establish a *prima facie* case of obviousness, the reference must disclose each and every element of the claims. As noted above, Domb 1 does not disclose poly(ester-anhydrides) with random ester and/or amide bonds in the polymer chain which are formed into a matrix incorporating a bioactive agent. Therefore, Domb 1 does not disclose every element of the claims. Further, it would not have been obvious to alter the structure of the poly(anhydride) of Domb to place random ester and amide bonds in the backbone to achieve the different structural and physical characteristics

associated with the claimed polymer. Therefore, claims 1 and 9, as amended, are not obvious over Domb 1.

In view of the art as a whole

Both Domb 1 and Teomim disclose polyanhydrides formed from diacids formed from ricinoleic acid esters. The resultant polymers do not have random ester or amide bonds in the backbone. The random ester in the backbone imparts different properties to the polymer of the claimed composition. Therefore, claims 1 and 9, as amended, are not obvious over Domb 1 and Teomim alone or in combination.

Allowance of claims 1-14 is respectfully solicited.

Double Patenting Rejection

Claims 1-10 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 57-61, 64, 65, 73-77 and 79-81 of copending Application Serial No. 10/433,143. Without making any admissions and solely for the purpose of facilitating prosecution, Applicants submit a Terminal Disclaimer.

Allowance of claims 1-14 is respectfully solicited.

Respectfully submitted,

___/Patrea L. Pabst/____
Patrea L. Pabst
Reg. No. 31,284

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PABST PATENT GROUP LLP
400 Colony Square, Suite 1200
1201 Peachtree Street
Atlanta, Georgia 30361
(404) 879-2151
(404) 879-2160 (Facsimile)